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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,538	08/17/2001	Steve J. D. Bell	37070/205236	5069

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EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/932,538

Applicant(s)

BELL ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 8-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4-11-05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 4-25-2005 has been entered.

The declaration filed on 1-26-2005 under 37 CFR 1.132 is acknowledged and has been fully considered. It is noted that the declaration refers to copending application 09/794,576. However, since the instant application and application 09/794,576 share a common parent and the issues addressed in both applications are the same, the declaration is deemed acceptable.

Claim Rejections Withdrawn

The rejection of claims 5-7 under 35 U.S.C. 102(b) as being anticipated by Relyveld (U.S. Patent 4,016,252 – IDS- 4/15/02) is withdrawn. The declaration of Dr. Relyveld filed on 1-26-2005 has been fully considered and deemed persuasive.

Claim Rejections Maintained and New Grounds of Rejection

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 5-7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for reasons of record.

Claim 5 is rendered vague and indefinite by the use of the phrase "induce immunity in a patient". It is still unclear what is meant by said phrase.

Applicant argues:

1. Said phrase, by its plain and simple meaning, means to induce an immunological response in a patient.

Applicant's arguments have been fully considered and deemed non-persuasive.

It is still unclear what immunological responses are encompassed by said term. Applicant argues that immunity refers to any immunological response, when in fact it is defined in the art as protection from infectious disease. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). Moreover, it is unclear to what, if anything, the immune response is directed. Is the immune response directed to the calcium phosphate particle or the "pharmacologically active agent"? Is the immune response specific or non-specific?

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-12 of copending Application No. 10/824,097. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 5-7 of the instant application are drawn to methods for inducing "immunity" in a patient comprising the administration of calcium phosphate particles that are at least partially coated with a "pharmacologically active agent". Claims 10-12 of copending application 10/824,097 are drawn to methods of inducing an immune response in a patient comprising the administration of calcium phosphate particles that are at least partially coated with an allergen and constitute a specific embodiment that renders the genus (i.e. the claims of the instant application) obvious. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1645

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is rendered vague and indefinite by the use of the terms "substantially spherical shape" and "substantially smooth surface". It is unclear what degree of smoothness or roundness is engendered by the term "substantial".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Nuwayser (U.S. Patent 5,648,097).

The instant claims are drawn methods of inducing immunity in a patient utilizing substantially smooth and substantially round calcium phosphate particles with a diameter ranging from 300 nm to 4000 nm at least partially coated and or impregnated with an antigen. Said particles are optionally used in compositions comprising said particles and a pharmaceutically acceptable carrier and other excipient wherein said particles are delivered to a mucosal surface.

Nuwayser discloses methods for adsorbing biologically active compounds to calcium

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phosphate particles wherein the resulting particles serve as controlled release drug delivery vehicles (see abstract, column 5 lines 16-36). Moreover, Nuwayser discloses that said particles are substantially spherical and substantially smooth (see column 3, lines 52-54). Nuwayser further discloses that the biologically active agent or drug can include multitude of compounds including antigens and vaccines. Finally, it should be noted that the disclosure by Nuwayser contemplates application to mucosal surfaces as the disclosed "biologically active agents" include antihistamines and decongestants (see column 6, lines 13-18).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Robert A. Zeman". The signature is fluid and cursive, with a large, stylized initial "R".

Robert A. Zeman

June 28, 2005